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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/830,838 | 01/08/2003 | Gerd Haberhausen | 18727-US | 3591 |
| 22798 | 7590 | 07/05/2005 | EXAMINER | |
| QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C. | | | MYERS, CARLA J | |
| P O BOX 458 | | | ART UNIT | |
| ALAMEDA, CA 94501 | | | PAPER NUMBER | |
| 1634 | | | | |
| DATE MAILED: 07/05/2005 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-------------------------|--------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/830,838 | HABERHAUSEN ET AL. |
| | Examiner Carla Myers | Art Unit 1634 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-21 is/are pending in the application.
 - 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) ____ is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) 1-21 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.

- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: ____.

RESTRICTION

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-12 and 21, drawn to methods for detection of HIV nucleic acids, classified in Class 435, subclass 5.
 - II. Claims 13-20, drawn to HIV oligonucleotides, classified in Class 536, subclass 24.32.
2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the instant case, the nucleic acids of invention II can be used in a materially different process, such as for synthesizing nucleic acids or peptides or for therapeutic purposes.
3. These inventions are distinct for the reasons given above and have acquired a different status in the art as demonstrated by their different classification and recognized divergent subject matter. Further, inventions I and II require different searches that are not co-extensive. A finding that one of the individual oligonucleotides of invention II is anticipated or obvious over the prior art would not necessarily extend to a finding that the method of invention I is also anticipated or obvious over the prior art. Similarly, a finding that the method of invention I is novel and unobvious over the prior art would not necessarily extend to a finding that one of the individual oligonucleotides of invention II

is also novel and unobvious over the prior art. Accordingly, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

4. Sequence Election Requirement Applicable to Inventions I and II

The claims have been presented in improper Markush format, as distinct products and distinct methods are improperly joined by the claims. Groups I and II read on patentably distinct inventions drawn to multiple nucleic acid sequences. The claims encompass oligonucleotides comprising distinct sequences from the LTR, gag and pol regions of HIV selected from the group consisting of SEQ ID NO: 1-13 and the subfragments of SEQ ID NO: 1-13 consisting of SEQ ID NO: 14-25. Each oligonucleotide constitutes a distinct chemical compound and each has a distinct functional property. Each oligonucleotide consists of a different nucleotide sequence, has a different melting temperature and a different specificity of hybridization. For example, an oligonucleotide comprising SEQ ID NO: 1 is chemically, structurally and functionally distinct from an oligonucleotide comprising SEQ ID NO: 13. A search for an oligonucleotide comprising SEQ ID NO: 1 would not be co-extensive with a search for an oligonucleotide comprising SEQ ID NO: 13. Further, a finding that an oligonucleotide comprising SEQ ID NO: 1, for example, is novel and unobvious over the prior art would not necessarily extend to a finding that an oligonucleotide comprising SEQ ID NO: 13 is also novel and unobvious over the prior art. Similarly, a finding that an oligonucleotide comprising SEQ ID NO: 1 is anticipated or obvious over the prior art would not

necessarily extend to a finding that an oligonucleotide comprising SEQ ID NO: 13 is also anticipated or obvious over the prior art.

Each of the combinations of oligonucleotides is also distinct from the individual oligonucleotides because the combination of oligonucleotides have distinct structural and functional properties. Additionally, a reference which renders obvious a single oligonucleotide will not necessarily also render obvious a different oligonucleotide or combination of oligonucleotides. Similarly, a search indicating that a particular combination of oligonucleotides is novel or unobvious would not extend to a holding that a single oligonucleotide or a different combination of oligonucleotides is also unobvious.

Accordingly, the oligonucleotides and combinations of oligonucleotides are thus deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Applicant is advised that this is a restriction requirement and should **not** be construed as an election of species.

In response to this restriction requirement, applicant should elect one sequence selected from the group consisting of SEQ ID NO: 1-13 and one subsequence, corresponding to the elected sequence, selected from the group consisting of SEQ ID NO: 14-25, or a particular combination of sequences (SEQ ID NO: 1-13) and corresponding subsequences (SEQ ID NO: 14-25).

5. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.** Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with

an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571)-272-0745.

The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866)-217-9197 (toll-free).

Carla Myers
June 28, 2005

Carla Myers
CARLA J. MYERS
PRIMARY EXAMINER